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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,197	09/27/2005	Funda Elger	K21722USWO (C038435/01913)	4609
7590 Stephen M Haracz Bryan Cave 1290 Avenue of the Americas New York, NY 10104			EXAMINER GREENE, IVAN A	
			ART UNIT 1619	PAPER NUMBER
			MAIL DATE 07/22/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,197	Applicant(s) ELGER ET AL.	
	Examiner IVAN GREENE	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/18/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Claims 1-13 are currently pending and are presented for examination on the merits.

All rejections and/or objections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 05/08/2009 were filed before the first office action. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. The disclosed IDS documents have been considered where in English.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Rejection maintained for claims 1-4, 6-8, and 10-13; and new ground of rejection for claims 5, 9 and 14-17: Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitchett et al. (WO 1999/11143) in view of and Perrier et al. (US 5,912,016) and Altemueller et al. (US 6,423,364) as evidenced by Gerrard (Trends in Food Science and Technology, 13, 2002, pgs. 391-399) and Rahman (Handbook of Food Preservation, Marcel Dekker, 1999).

Applicants claim

Applicant claims stable powderous formulations comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked. Applicants further claim a method of preparing a powderous formulation comprising the steps of preparing an aqueous emulsion, adding a reducing sugar, affecting cross-linking by heating or enzymatic treatment with transglutaminase and drying the formulation to form a powder.

Determination of the scope and content of the prior art (MPEP 2141.01)

Fitchett et al. teaches lupin protein compositions (abstract), which are vegetable protein concentrates (50-90% protein), and protein isolates (90+% protein) are widely used in the food industry (pg. 1, lines 9-15). Fitchett et al. further teaches, "Lupins have

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long been recognized as a viable alternative to soya as a source of vegetable protein for human consumption" (pg. 2, line 7). Fitchett et al. further teaches, "It has long been known that the protein content of lupin seeds is equal to that of whole soya beans, and it has been exploited for years as a sources of (non-functional) protein in animal feeds" (pg. 2, lines 12-14). Fitchett et al. further teaches "lupin concentrates and isolates per se are known...and theses isolates/concentrates are also known to affect the chemical/physical behavior of foodstuffs in which they are incorporated" (pg. 2, lines 15-17).

Fitchett et al. teaches an emulsion comprising lupin protein composition, water and fat (pg. 2, line 35), where the emulsion may contain any suitable ratio of protein composition, water and fat (pg. 3, line 1). Fitchett notes that by "fat" is meant fats which are liquid at room temperature and, "often referred to as oils" (pg. 2, line 38 & pg. 3, line 1). Fitchett further teaches the example wherein palm fat is used (pg. 3, line 28). Fitchett et al. further teaches, the lupin protein is preferably present in substantially native form which is associated with higher functionality (pg. 4, lines 10-12). Fitchett et al. further teaches the examples of products covered by the invention including a fat-filled powder (pg. 4, lines 32-33). Fitchett et al. further teaches, "It may be desirable to derivatize or physically modify the lupin protein, for example...denaturing the proteins...by heating...or by partial...enzymatic digestion" (pg. 6, lines 8-10).

**Ascertainment of the difference between
the prior art and the claims (MPEP 2141.02)**

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The difference between the rejected claims and Fitchett et al. is that Fitchett et al. does not expressly teach cross-linking the lupin protein nor a specific fat-soluble active ingredient of neither claim 6 nor a process for preparing a powder formulation. The deficiency in cross-linking the lupin protein and a fat-soluble ingredient is cured by Perrier et al.; and the deficiency in powdered formulation is cured by Altemueller et al. Rahman provides motivation for producing a powder formulation and Gerrard teaches the chemistry of protein-protein crosslinking including Maillard and transglutaminase initiated cross-linking.

Perrier et al. teaches particles of cross-linked plant proteins (title) wherein the particles "...encapsulate substances, particularly active principles, including lipophilic active principles such as vegetable, mineral or synthetic oil, vitamin A and vitamin E derivatives..." (col. 8, lines 38-41). Perrier et al. further teaches it is well known in the art that encapsulation of active ingredients has the advantages of protecting the ingredients as well as controlling the release rate at the site of use (col. 1, lines 12-15). Perrier et al. further teaches the example in which microcapsules with a wall formed of crosslinked lupin proteins is made by dissolving sweet white lupin flour in water containing a succinate buffer of pH=6, the mixture is heated, the supernatant is separated, glucose is added emulsification and crosslinking are then carried out (example 9).

Altemueller et al. teaches a novel functional food ingredient comprising an unrefined plant protein material wherein the functional food ingredient is hydrated, partially denatured and dried (abstract). Altemueller et al. further teaches, "The plant protein material may be any unrefined protein material derived from a

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plant...Representative...examples of such plant protein materials include...lupin protein containing materials..." (col. 5 line 67, col. 6 lines 1 & 3-5). Altemueller et al. further teaches drying of the processed plant protein material, "The flash vaporized unrefined soy protein material slurry may be spray-dried to produce the dry unrefined soy protein material food ingredient of the present invention" (col. 26, lines 33-35).

Rahman gives several motivations for producing a powder formulation including, "...to increase shelf life, reduce packaging and storage costs, lower shipping weights, improve sensory attributes, encapsulate flavors, and preserve nutritional value in some cases" (pg. 173, paragraph 3).

Gerrard teaches protein-protein crosslinking in food (title) which comprises formation of covalent bonds between polypeptide chains within a protein or between proteins (pg. 391, col. 2, lines 24-27). Gerrard further teaches, "Food processing often involves high temperatures, extremes in pH, particularly alkaline, and exposure to oxidizing conditions and uncontrolled enzyme chemistry. Such conditions result in the introduction of protein crosslinks, producing substantial changes in the structure of proteins, and therefore the functional and nutritional properties of the final product." (pg. 391, col. 2, lines 38-45). Gerrard further teaches different types of crosslinking including, disulfide crosslinks (pg. 392) crosslinks derived from the Maillard reaction (heat initiated) and crosslinks formed via the enzyme transglutaminase (also see Figures 1 & 2).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

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It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Fitchett et al. with the teachings of Perrier et al. and Altemueller et al. because they each teach plant protein compositions for use in food products. The processing of foods, which is common place in modern society, provides for an increased shelf life, consistent and appealing texture, and enhanced flavor. Cross-linking of proteins provides a means for controlling the functional properties of foods, such as the texture. A cross-linked protein can also provide a matrix for additional beneficial ingredients such as fat-soluble vitamins. A dry powdered product would be very desirable for functional proteins for use as food additives because the storage conditions would be more favorable and the shipping costs would be reduced. It would have been prima facie obvious at the time of the claimed invention that a cross-linked protein would provide for an enhanced food additive. It would have been prima facie obvious that vitamin enrichment would provide for a more nutritious and therefore desirable product. It would have been prima facie obvious at the time of the claimed invention to produce a powder formulation from the emulsion taught by Perrier et al. because the shelf life would increase and the shipping costs would decrease adding value to the product. Furthermore, it is prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, i.e. a plant protein powder. See MPEP 2144.06.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success, for example the prior art teaches cross-linking of different proteins using various methods, as discussed above. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments:

Applicant's arguments filed 05/04/2009 have been fully considered but they are not persuasive.

Applicant's argument that there is no suggestion or motivation for cross-linking of protein in a matrix provided by Fitchett et al., is not convincing because Fitchett et al. is not relied upon for this teaching. Perrier et al. teaches particles of cross-linked plant proteins (title) and when combine with Fitchett et al. suggests cross-linked lupin protein formulations.

Applicant's argument that there is no suggestion or motivation in Fitchett et al. for the claimed powderous formulation to comprise a fat-soluble active ingredient, is not convincing because Fitchett et al. is not relied upon for this teaching. Perrier et al. teaches the inclusion of lipophilic active and the encapsulation of active ingredients

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(8:38-41) and when combine with Fitchett et al. suggests lupin protein formulations comprising an encapsulated fat soluble active ingredient.

Applicant's argument that there is no suggestion or motivation in Fitchett et al. to produce powderous formulations, is not convincing because Fitchett et al. is not relied upon for this teaching. Altemueller et al. teaches dried powderous unrefined soy protein material food ingredient (26:33-35) and when combined with Fitchett et al. suggests dried powderous formulations comprising lupin proteins.

Applicant's argument that none of Fitchett, Perrier, or Altemueller disclose or suggest a formulation of a fat-soluble active ingredient in powder form, is not convincing because the references are relied upon as a combination. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant's argument that Gerrard provides no disclosure that the cross-linking can be applied to lupin protein, is not convincing because the reactions taught by Gerrard can be applied to "food protein, either native or denatured" (see p. 392, Figure 1) and the described reactions would clearly apply to lupin food protein.

Applicant's argument that achieving a stable powderous formulation would not have been predictable to one of skill in the art, is not convincing because Altemueller et al. further teaches drying of the processed plant protein material (26:33-35), and it would have been obvious to the skilled artisan that powderous form would have been

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more stable than liquid formulations because chemical products, especially easily degradable food products, would have degraded more slowly in the dried form (i.e. a more stable product).

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 6-9, 11 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 8, 12-14, 16 and 17 of copending Application No. 10/564,635 (hereafter referred to as ‘635) in view of Perrier et al. (US 5,912,016).

Instant claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix formed from native lupin protein composition wherein the protein in the matrix is cross-linked; instant claim 11 recites, a process wherein a

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reducing sugar is added and the composition is submitted cross-linking by heating. Instant claim 6 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or carotenoids, or a polyunsaturated fatty acid; instant claim 7 recites form formulations wherein the fat-soluble active ingredient is mixed with a plant or animal fat. Instant claims 6 and 7 are coextensive in scope with copending '635 claims 12 and 13. Instant claim 8 recites formulations wherein the reducing sugar is glucose, fructose, saccharose, or xylose. Copending '635 claim 14 recites, formulations wherein the reducing sugar is glucose, fructose, saccharose, or xylose. Instant claim 8 is coextensive in scope with copending '635 claim 14. Instant claim 13 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the native lupin protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein by heat treatment or by treatment with a cross-linking enzyme.

Copending '635 claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix of milk protein compositions, wherein the protein is thermally cross-linked with a reducing-sugar. Copending '635 claims 6 recites the formulation additionally comprises a plant protein and copending '635 claim 8 recites formulations which further comprise plant protein which is obtained from potato protein, soy protein, wheat protein, pea protein, rice protein or lupin protein. Copending '635 claim 12 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or a carotenoid, or a polyunsaturated fatty acid; copending '635 claim 13 recites formulations wherein the fat-soluble active ingredient is mixed with a plant or animal fat.

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Copending '197 claim 17 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the milk protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein with heat treatment.

The difference between Copending '635 and the instant claimed invention is that copending '635 does not explicitly teach the use of lupin protein for the primary cross-linking protein. The deficiency of using a lupin protein is cured by the teachings of Perrier et al., which teaches particles of cross-linked lupin plant proteins wherein the particles encapsulate active substances, including lipophilic active principles, as discussed above.

It would have been prima facie obvious to combine copending '635 with the teachings of Perrier et al. and produce the instant claimed invention because both applications teach cross-linked protein food additives with a fat-soluble active ingredient in the protein matrix. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, i.e. a cross-linked protein food additive. See MPEP 2144.06. Furthermore, the lupin protein of Perrier et al. would provide an added nutritive value to copending '635 and produce a more desirable product. It would be obvious to substitute the milk protein of '635 with the lupin protein of the instant application because it would provide access to a new market of consumers for which the milk protein would be unacceptable (e. g. vegans). Examiner notes the comprising language of the instant application invites additional ingredients.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments:

Applicant's arguments filed 05/04/2009 have been fully considered but they are not persuasive. The Examiner thanks Applicant for pointing out the Bewert et al. was stated in error the correct reference is Perrier et al. as indicated in Applicants response to this rejection.

Applicant's argument that Perrier simply does not disclose or suggest a formulation of a fat-soluble active ingredient in powder form, is not convincing because the copending claims of '635 recite --stable powderous formulations--, coextensive with the preamble of the instantly rejected claims.

Conclusion

Claims 1-17 are pending and have been presented for examination on the merits. Claims 1-17 are rejected under 35 USC § 103(a). Claims 1, 6-9, 11 and 13 are provisionally rejected on the grounds of nonstatutory double patenting over copending Application No. 10/564,635.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-5868. The examiner can normally be reached on Monday through Thursday 7AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IVAN GREENE
Examiner, Art Unit 1619

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616